DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#21

AUG 13 1992

Re: Plendil®
Docket No. 91E-0377

The Honorable Douglas B. Comer
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Comer:

This is in regard to the patent term extension application for U.S. Patent No. 4,264,611 filed by Aktiebolaget Astra under 35 U.S.C. 156. The patent claims the human drug product Plendil®, NDA 19-834.

In the December 19, 1991, issue of the Federal Register, the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before June 16, 1992, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. FDA, therefore, considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Edward V. Filardi, Esq.
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